NATIONAL BUREAU OF STANDARDS REPORT

5754

Progress Report

on

PROPOSED SPECIFICATION
for
IMPRESSION MATERIALS; SYNTHETIC RUBBER BASE,
DENTAL

by

W. A. C. Miller, Jr.
William C. Hansen
George Dickson
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U. S. DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS

THE NATIONAL BUREAU OF STANDARDS

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U. S. DEPARTMENT OF COMMERCE

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PROPOSED SPECIFICATION
for
IMPRESSION MATERIAL; SYNTHETIC RUBBER BASE, DENTAL

Introduction

The proposed specification for synthetic rubber base impression materials is based to a large extent on data reported in a paper by the same authors [Some Physical Properties of Synthetic Rubber-Based Dental Impression Materials]. Test procedures for permanent deformation and strain are similar with some modifications to procedures described in Federal Specification U-I-496a for Impression Material, Hydrocolloidal, Agar Type, Dental; Federal Specification U-I-498 for Impression Material, Hydrocolloidal, Alginate Type, Dental and American Dental Association Specification No. 11 for Hydrocolloidal Impression Material, Agar Type. Determinations of permanent deformation and strain are made at approximately 8 to 10 minutes after the material is mixed and thus serve indirectly as requirements that the material set within this period.

Since dimensional stability has been one of the most widely acclaimed features of the synthetic rubber based materials, a requirement for this property has been included.

Two types of material, silicone base and Thiokol base, are listed in the specification. Although all requirements included are identical for both types; mixing and handling characteristics do differ and the type to be obtained should be left to the choice of the purchaser.

1. SCOPE AND CLASSIFICATION:

1.1 Scope. -- This specification covers dental impression material with a synthetic rubber base, intended primarily for taking oral impressions.

1.2 Classification.

1.2.1 Grade and Type. -- Impression materials covered by this specification shall be of one grade and of the following types as specified in the invitation for bids:

Type I Silicone base.
Type II Thiokol base.

2. APPLICABLE SPECIFICATIONS AND STANDARDS:

2.1 There are no other specifications or standards applicable to this specification.

3. REQUIREMENTS:

3.1 Material. -- The impression material shall be uniform in consistency and free of foreign materials and impurities. The manufacturer shall furnish a certificate stating that the material contains no poisonous ingredients in sufficient concentration to be harmful to human beings when used as directed.

3.1.1 Suitability. -- The material when mixed as directed by the manufacturer's instructions accompanying the package, shall be suitable for taking impressions in the oral cavity, or for reproducing dental models.

3.2 Amount of material in an individual package. -- The amount of material in each package shall be such that, when the contents are mixed in accordance with the manufacturer's directions, the resulting mix shall have a volume of not less than 130 ml when measured to the nearest millileter.

3.3 Mixing time. -- The mixing time as stated in the manufacturer's directions shall not exceed 1 minute.

3.4 Working time. -- The working time when tested as specified in 4.3.2 shall be not less than 2 minutes.

3.5 Detail reproduction. -- The material shall reproduce a line 0.0015 inch in width when tested by the method of 4.3.3.

3.6 Compatibility. -- The material shall be compatible with gypsum model and investment materials and shall reproduce a line 0.0015 inch in width when tested by the method of 4.3.4.

3.7 Permanent deformation after compression. -- The permanent deformation when tested as specified in 4.3.5 shall not exceed 4.0 percent.

3.8 Strain in compression. -- The strain shall be not less than 4.0 percent nor more than 30.0 percent between a stress of 100 grams per square centimeter (1.42 pounds per square inch) and a stress of 1,000 grams per square centimeter (14.2 pounds per square inch).

3.9 Dimensional stability. -- Linear change shall be not more than 0.2 percent when measured at 6 hours from the beginning of the mix by the method specified in 4.3.7.

3.10 Deterioration. -- The permanent deformation as tested in 4.3.5 shall not exceed 4.0 percent after the material has been stored at 60°± 1°C (140°± 1.8°F) for 1 week and tested in accordance with 4.3.8.

3.11 Instructions for use. -- Adequate and accurate instructions shall accompany each package. These shall include the proportions of material needed for proper mixing, the mixing time, the working time at 22± 1°C and a relative humidity of 60± 5%, and the minimum time for leaving the impression in the mouth.

4. SAMPLING, INSPECTION AND TEST PROCEDURES:

4.1 Sampling. -- Unless otherwise specified, two or more units shall be taken at random from each lot or batch of material included in the delivery. The number of units taken shall be sufficient to provide a total sample of at least 300 ml.

4.2 Inspection. -- Each unit taken as part of the sample of 4.1 shall be inspected for compliance with the requirements of sections 3.1 and 5.

4.3 Physical tests.

4.3.1 Standard testing conditions. -- All physical tests shall be made under uniform atmospheric conditions of 22° ± 1.0°C (71.6° ± 1.8°F) temperature and 60 ± 5 percent relative humidity. Equipment and material shall be conditioned in the testing room for not less than 12 hours prior to making the tests. Material shall be mixed according to the manufacturer's instructions.

4.3.2 Working time. -- Compliance with the requirement of 3.4 shall be determined by a penetration test. A penetrometer using a cylindrical flat-ended needle 4 millimeters in diameter and a load of 50 grams and having a dial indicator accurate to 0.001 inch shall be used for this test. A smooth flat

plate shall be placed under the needle and a fiducial reading made. A ring, 5/8 in. high and approximately 1-1/8 in. inside diameter shall be placed upon the plate beneath the needle and filled with material. The top surface shall be leveled. At 2 minutes from the start of the mix, the needle shall be placed in contact with the top surface of the material and released. At 10 seconds after release, an indicator reading shall be made. The difference between the two readings shall be not more than 0.010 in. All readings shall be made to the nearest 0.001 in.

4.3.3 Detail reproduction. -- A ring of the type specified in 4.3.2 shall be positioned on a test block similar to that shown in Figure 1 so that the intersection of a crossline and a 0.0015 inch width line is in the center of the ring. The ring shall be slightly overfilled with a mix of impression material. A flat plate shall be placed on top and the excess material squeezed out. At 2 minutes from the start of mix, the entire assembly shall be placed in a water bath maintained at a temperature of 37° ± 1°C. At 7-1/2 minutes from the start of the mix, the assembly shall be removed from the bath. The ring with the impression material shall be separated from the plate immediately, and the impression shall be examined under low angle illumination without magnification. The reproduction shall be considered to be satisfactory if the 0.0015 inch width line is continuous and unbroken for the full width of the ring.

4.3.4 Compatibility. -- A gypsum model shall be poured against the impression made in 4.3.3 within 10 minutes from the time it is separated from the test block. The gypsum model material used shall be capable of reproducing a line 0.0015 inch in width when tested against the test block shown in Figure 1. The gypsum and impression material shall be separated after the gypsum has reached its final set. The model shall be examined under low angle illumination without magnification. The impression material shall be considered to be compatible with the gypsum product if the 0.0015 inch width line is reproduced unbroken in the gypsum for the full width of the ring.

4.3.5 Permanent deformation.

4.3.5.1 Preparation of the test specimen.-- A lubricated metal mold, 0.5 inch inside diameter, 1 inch outside diameter, and 0.75 inch high shall be overfilled with impression material. The mold shall be placed on a flat surface and a flat plate shall be pressed on top of the mold to remove the excess material. At 2 minutes from the beginning of the mix the mold and accompanying plates shall be immersed in a 37°C water bath. At 7-1/2 minutes from the beginning of the mix the specimen shall be separated from the mold and at 8 minutes it shall be tested by the method specified in 4.3.5.2.

4.3.5.2 Test procedure. -- The specimen shall be placed in an instrument consisting essentially of a dial gauge sensitive to 0.001 inch mounted to a steady base and equipped with a screw positioned in such a manner that sufficient pressure can be applied to the specimen to produce the required amount of strain. At 8 minutes from the beginning of the mix a lightweight plate shall be placed on top of the specimen and the foot of the dial gauge shall be allowed to contact the plate. The weight of the plate and the force of the spring in the gauge shall be 50 ± 5 grams. The dial gauge shall be read 30 seconds after the foot of the gauge contacts the plate and the value recorded as "Reading A." The dial gauge foot shall be lowered 0.090 inch by means of a screw and shall be maintained in this position on the specimen for 1 minute, then the foot at the dial gauge shall be raised and the specimen allowed to rest under no load for 1 minute. The dial gauge foot shall again be allowed to contact the plate on the specimen for 30 seconds and a second reading shall be taken. This value shall be recorded as "Reading B." The difference between "Reading A and Reading B" in inches divided by 0.75 inches, (considered to be the original length of the specimen) and multiplied by 100 shall be considered to be the percent permanent deformation.

The value shall be reported as the average of tests on three specimens and shall be recorded to the nearest 0.1 percent.

4.3.6 Strain in compression. -- The specimen prepared as in 4.3.5.1 shall be transferred to an appropriate instrument and shall be subjected to a load calculated to produce a stress of 100 grams per square centimeter (1.42 pounds per square inch). Thirty seconds later the dial indicator shall be read. This value shall be designated as "Reading A." Sixty seconds after application of a stress of 100 grams per square centimeter, an additional load calculated to produce a total stress on the specimen of 1000 grams per square centimeter (14.2 pounds per square inch) shall be gradually applied during an interval of 10 seconds. Thirty seconds after initiation of the application of this load, a reading of the dial indicator shall be taken. This reading shall be designated as "Reading B." The difference between "Reading A" and "Reading B" in inches, divided by 0.75 inches (considered to be the original length of the specimen) and multiplied by 100 shall be considered to be the percent of strain between the stresses of 100 grams per square centimeter and 1000 grams per square centimeter.

The value shall be reported as the average of tests on three specimens and shall be recorded to the nearest 0.1 percent.

4.3.7 Dimensional stability.

4.3.7.1 Preparation of the mold. -- The mold may be made from metal, polymethyl methacrylate or Teflon as shown in Figure 2.

4.3.7.2 Preparation of the specimen. -- The mold shall be lubricated with silicone grease and placed on a flat surface which has been covered with a sheet of 0.001 inch thick polyethylene. Two small pieces of polished metal on which crosslines have been ruled shall be placed polished surfaces down, as near as possible to each end of the mold (but not less than 1-3/4 inches apart). The metal pieces may be held in position with

minute quantities of utility wax or similar substances. The mold shall be slightly overfilled with impression material. Another sheet of 0.001 inch polyethylene shall be placed over the impression material and the excess pressed out with a flat plate. When the material has set, the polyethylene shall be stripped off and the flash trimmed away before separating the halves of the mold.

4.3.7.3 Test procedure. -- The specimen shall be dusted with talc on its contacting or bottom surface and placed on a smooth glass surface which has also been dusted with talc. The distance between the crosslines on the two pieces of metal shall be measured with a measuring microscope at 15 minutes from the beginning of the mix and at 6 hours from the beginning of the mix. The difference between the two measurements shall not exceed 0.2 percent of the distance between the crosslines at 15 minutes from the beginning of the mix.

The value shall be reported as the average of tests on three specimens and shall be based on measurements to the nearest 0.001 inch.

4.3.8 Deterioration test. -- At least three unopened packages of the material shall be stored at 60° ± 1°C (140° ± 1.8°F) for one week. At the end of the storage period, test specimens shall be made and tested for permanent deformation in accordance with 4.3.5.

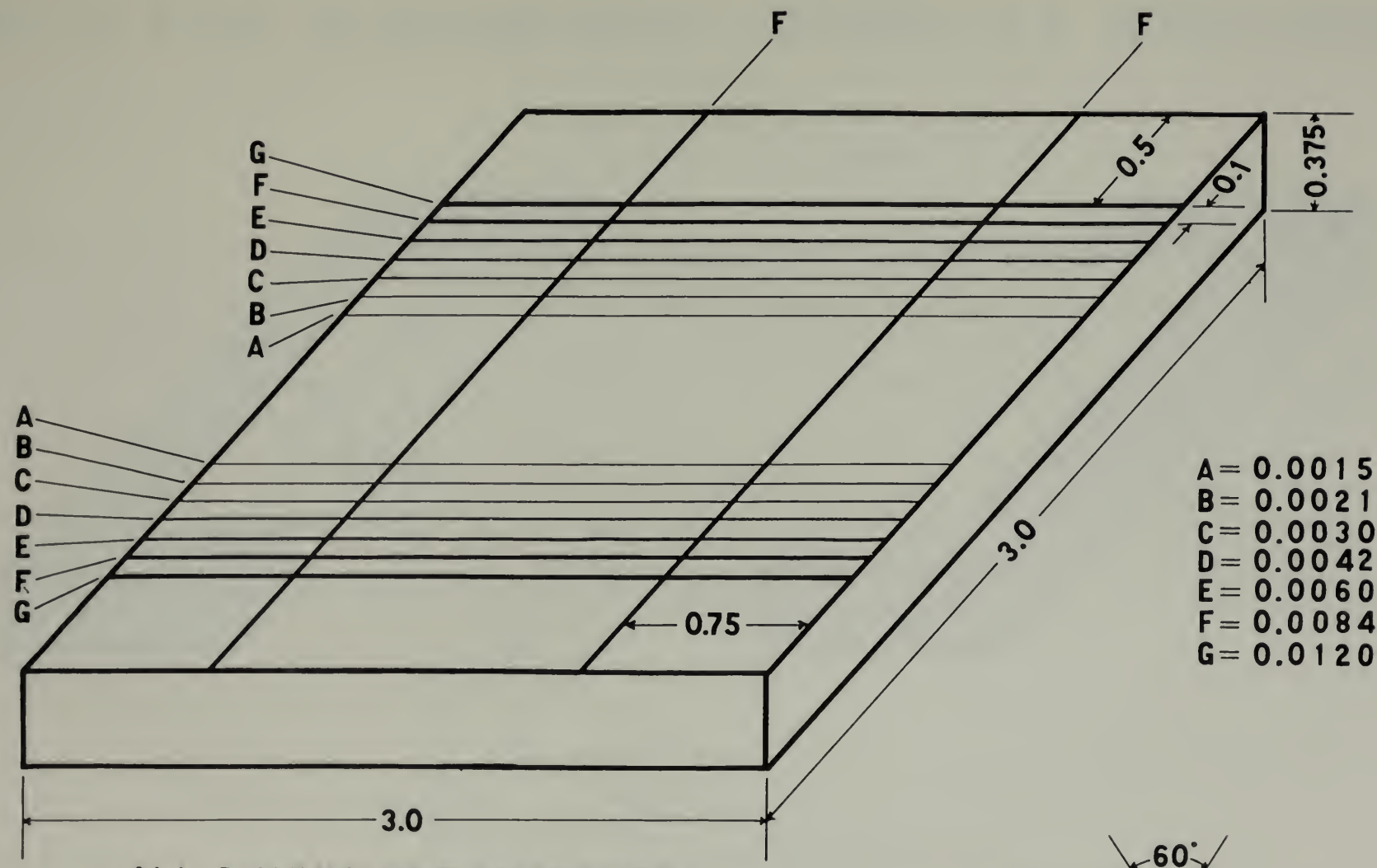
4.4 Compliance. -- Each lot or batch of material included in the delivery shall be accepted or rejected individually. If the sample (4.1) complies with all of the requirements of this specification the lot or batch shall be accepted. If the sample fails to comply with any requirement, two additional samples shall be selected and tested. If both comply with all requirements, the lot or batch shall be accepted; otherwise, the lot or batch shall be rejected.

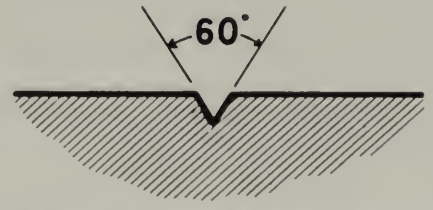
5. PREPARATION FOR DELIVERY:

5.1 Packaging. -- The material shall be supplied in sealed airtight containers from which no leakage shall be discernible.

5.1.1 Instructions. -- Adequate and accurate instructions for manipulation and use of the material shall accompany each package. (See 3.11).

TEST BLOCK FOR DETAIL REPRODUCTION TEST





CROSS SECTION
OF RULED LINES

Figure 1.

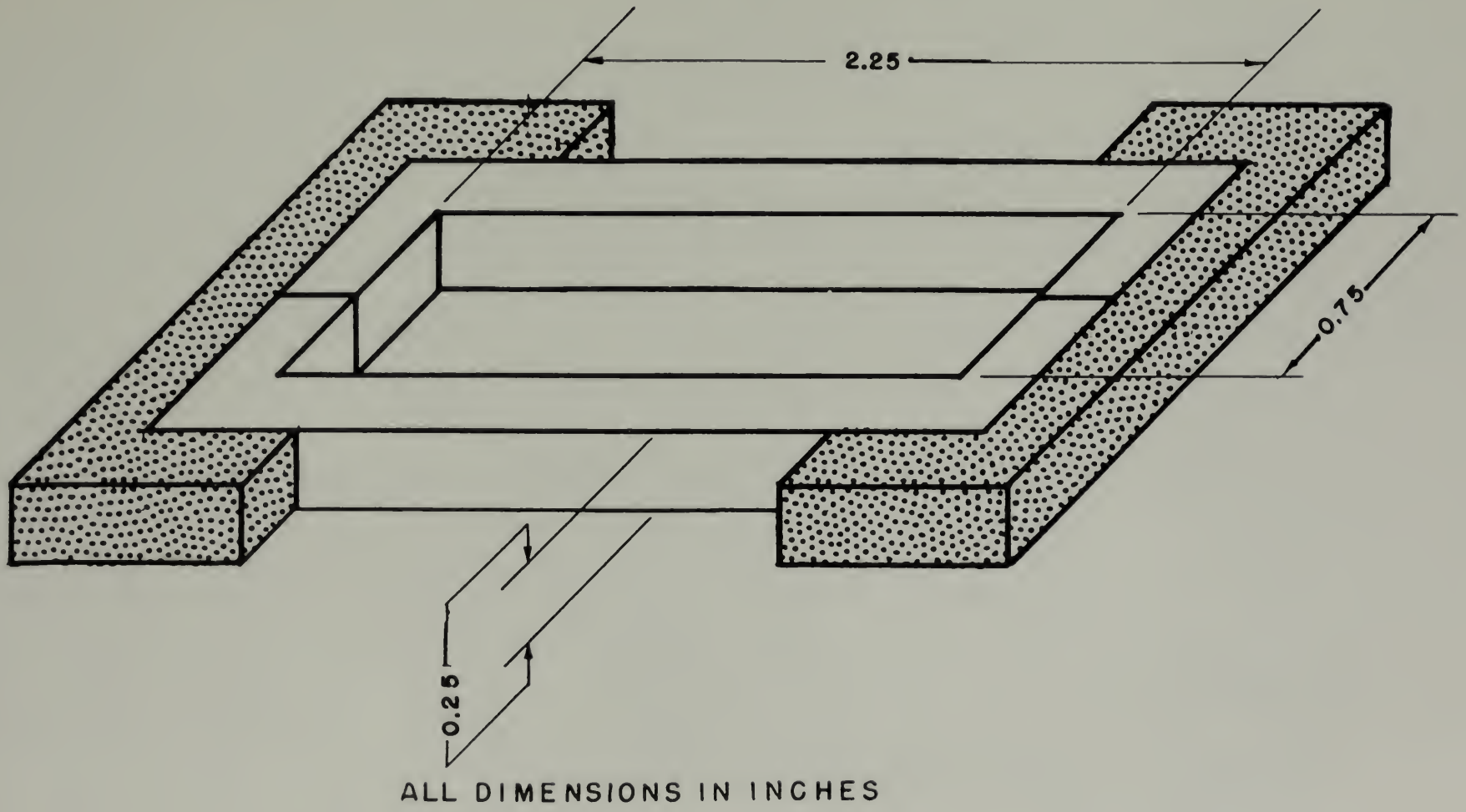

MOLD FOR DIMENSIONAL STABILITY SPECIMEN
2.25
0.75
0.25
ALL DIMENSIONS IN INCHES

Figure 2.

U. S. DEPARTMENT OF COMMERCE
Sinclair Weeks, *Secretary*

NATIONAL BUREAU OF STANDARDS
A. V. Astin, *Director*

THE NATIONAL BUREAU OF STANDARDS

The scope of activities of the National Bureau of Standards at its headquarters in Washington, D. C., and its major laboratories in Boulder, Colo., is suggested in the following listing of the divisions and sections engaged in technical work. In general, each section carries out specialized research, development, and engineering in the field indicated by its title. A brief description of the activities, and of the resultant publications, appears on the inside front cover.

WASHINGTON, D. C.

Electricity and Electronics. Resistance and Reactance. Electron Devices. Electrical Instruments. Magnetic Measurements. Dielectrics. Engineering Electronics. Electronic Instrumentation. Electrochemistry.

Optics and Metrology. Photometry and Colorimetry. Optical Instruments. Photographic Technology. Length. Engineering Metrology.

Heat. Temperature Physics. Thermodynamics. Cryogenic Physics. Rheology. Engine Fuels. Free Radicals Research.

Atomic and Radiation Physics. Spectroscopy. Radiometry. Mass Spectrometry. Solid State Physics. Electron Physics. Atomic Physics. Neutron Physics. Nuclear Physics. Radioactivity. X-rays. Betatron. Nucleonic Instrumentation. Radiological Equipment.

Chemistry. Organic Coatings. Surface Chemistry. Organic Chemistry. Analytical Chemistry. Inorganic Chemistry. Electrodeposition. Molecular Structure and Properties of Gases. Physical Chemistry. Thermochemistry. Spectrochemistry. Pure Substances.

Mechanics. Sound. Mechanical Instruments. Fluid Mechanics. Engineering Mechanics. Mass and Scale. Capacity, Density, and Fluid Meters. Combustion Controls.

Organic and Fibrous Materials. Rubber. Textiles. Paper. Leather. Testing and Specifications. Polymer Structure. Plastics. Dental Research.

Metallurgy. Thermal Metallurgy. Chemical Metallurgy. Mechanical Metallurgy. Corrosion. Metal Physics.

Mineral Products. Engineering Ceramics. Glass. Refractories. Enameled Metals. Concreting Materials. Constitution and Microstructure.

Building Technology. Structural Engineering. Fire Protection. Air Conditioning, Heating, and Refrigeration. Floor, Roof, and Wall Coverings. Codes and Safety Standards. Heat Transfer.

Applied Mathematics. Numerical Analysis. Computation. Statistical Engineering. Mathematical Physics.

Data Processing Systems. SEAC Engineering Group. Components and Techniques. Digital Circuitry. Digital Systems. Analog Systems. Application Engineering.

• Office of Basic Instrumentation.

• Office of Weights and Measures.

BOULDER, COLORADO

Cryogenic Engineering. Cryogenic Equipment. Cryogenic Processes. Properties of Materials. Gas Liquefaction.

Radio Propagation Physics. Upper Atmosphere Research. Ionospheric Research. Regular Propagation Services. Sun-Earth Relationships. VHF Research.

Radio Propagation Engineering. Data Reduction Instrumentation. Modulation Systems. Navigation Systems. Radio Noise. Tropospheric Measurements. Tropospheric Analysis. Radio Systems Application Engineering. Radio Meteorology.

Radio Standards. High Frequency Electrical Standards. Radio Broadcast Service. High Frequency Impedance Standards. Calibration Center. Microwave Physics. Microwave Circuit Standards.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